REMARKS

This amendment is responsive to the Office Action dated March 23, 2006. Applicant has amended claims 1 and 46. Claims 1-50 remain pending.

Rejection for Statutory Double Patenting:

The Examiner provisionally rejected claims 1-45 under 35 U.S.C. §101 as claiming the same invention as that of claims 1-43 of copending Application Serial No. 10/718,038 (U.S. Patent Application Publication 2005/0049663). Applicant notes that Application Serial No. 10/718,038 is presently abandoned. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

Claim Rejection Under 35 U.S.C. § 112

In the Office Action, the Examiner rejected claims 1-15 and 44-50 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has amended claims 1 and 46 for purposes of clarification. Applicant submits that claims, as amended, particularly point out and distinctly claim the subject matter, as required by 35 U.S.C. §112, second paragraph.

Claim Rejection Under 35 U.S.C. § 103

As a preliminary matter, in the rejection under 35 U.S.C. §103, the Office Action has failed to provide an articulated rationale supported by evidence that would allow Applicant to provide a detailed and reasoned response regarding a variety of issues, thereby furthering the prosecution of the application. Applicant points out that the Office Action is required to provide "reasons for [a] rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application."[1] Applicant submits that the Office Action dated March 23, 2006 fails to meet this standard. For example, the Office Action failed to address elements recited in the independent claims, as well as a number of the dependent claims. In the event the rejection of the pending claims is maintained, Applicant requests that any subsequent Office Action provides greater

[1] 35 U.S.C. 132(a).

detail in regarding such rejections. In particular, Applicant requests any subsequent Office Action point to specific elements in the prior art that are deemed to meet elements recited in Applicant's claims, and correlate the specific elements in the prior art to such elements recited in Applicant's claims.

In the Office Action, the Examiner rejected claims 1-22 and 24-50 under 35 U.S.C. §103(a) as being unpatentable over US 2002/0147485 by Mamo et al. (Mamo) in view of US 6,146,371 to DeWindt et al. (DeWindt). The Examiner also rejected claim 23 under 35 U.S.C. §103(a) as being unpatentable over the modified Mamo, as applied to claims 1-22 and 24-45 above, in further view of US 5,255,691 to Otten (Otten). Applicant respectfully traverses these rejections. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Independent Claim 1

With respect to independent claim 1, the applied references fail to disclose or suggest a stimulation lead introducer comprising an elongated dilator, wherein at least a portion of the conical distal tip of the dilator has a substantially oblong cross-section. In the rejection of claim 1, the Office Action acknowledged that Mamo fails to disclose an elongated dilator with an oblong cross-section, but stated that DeWindt would have made it obvious to modify a dilator of Mamo to have an oblong cross-section.

To establish prima facie case of obviousness, the Office Action is required to demonstrate that the applied references teach or suggest all the claim limitations.[2] However, neither Mamo nor DeWindt suggests an elongated dilator, wherein at least a portion of the conical distal tip has a substantially oblong cross-section. The Office Action admitted that Mamo fails to disclosure such a feature. Furthermore, DeWindt fails to even *discuss* a dilator.

Instead, DeWindt discloses a cannula for use in conducting fluid to or from a body.[3] The DeWindt cannula is not an elongated dilator. Accordingly, neither Mamo nor DeWindt discloses or suggests an elongated dilator, wherein at least a portion of the conical distal tip has a substantially oblong cross-section, as required by independent claim 1.

[2] MPEP §706.02(j).

Furthermore, the teachings of DeWindt would not have suggested modification of the shape of the Mamo dilator to a person of ordinary skill in the art. The Office Action stated that the motivation to modify the dilator of Mamo with the oblong or oval shape of DeWindt would be to utilize available space more efficiently. DeWindt teaches use of an oval-shape in a cannula to provide an equivalent flow rate to that of a round cannula, while not extending as far toward the center of an access aperture, which is helpful to provide space outside of the cannula for other uses of the access aperture.[4]

This teaching would not have suggested any modification of the Mamo dilator. Use of the Mamo dilator does not involve considerations of flow rate. Moreover, use of the Mamo dilator does not require any space outside of the dilator but within an access aperture.[5] Accordingly, a person of ordinary skill would have seen no reason to modify the Mamo dilator based on the DeWindt teachings.

It appears that the Office Action found DeWindt to be relevant *merely* because it discloses an oval shape. However, a person of ordinary skill would not have considered any feature of the cannula disclosed in DeWindt to be relevant to a dilator as disclosed in Mamo. The Office Action provided no rationale or evidence as to why a person of ordinary skill would have turned to the DeWindt cannula for modification of the Mamo introducer. Accordingly, it appears that the Office Action impermissibly used Applicant's disclosure as a blueprint to combine attributes of two unrelated devices and thereby reproduce the Applicant's invention.

For at least these reasons, the Office Action has failed to provide a prima facie case of obviousness for claim 1 as required to support a rejection under 35 U.S.C. §103(a). Applicant respectfully requests withdrawal of the rejection of claim 1 and dependent claims 2-15, 44 and 45.

Independent Claim 16

As discussed with respect to independent claim 1, the applied references fail to disclose or suggest an elongated dilator, wherein at least a portion of the conical distal tip has a substantially oblong cross-section. Specifically, neither Mamo nor DeWindt discloses such a

---

[3] *See*, e.g., DeWindt et al., column 1, lines 41-42.
[4] DeWindt et al., column 3, line 66 – column 4, line 5.
[5] *See*, Mamo et al. FIG. 6i and paragraph [0085].

feature, and the teachings of DeWindt would not have suggested modification of the Mamo dilator.

Claim 16 also contains additional elements not addressed by the Office Action which are not taught or suggested by either Mamo or DeWindt. For example, Mamo and DeWindt fail to disclose or suggest inserting a stimulation lead introducer into an epidural region proximate a spine of a patient via a guidewire. In contrast, Mamo discloses implantation of a sacral stimulation lead through a foramen of the sacrum in a patient.[6]

For at least these reasons, the Office Action has failed to provide a prima facie case of obviousness for claim 16 as required to support a rejection under 35 U.S.C. §103(a). Applicant respectfully requests withdrawal of the rejection of claim 16 and dependent claims 17-37.

Independent Claim 38

As discussed with respect to independent claim 1, the applied references fail to disclose or suggest a dilator, wherein at least a portion of the conical distal tip has a substantially oblong cross-section. Specifically, neither Mamo nor DeWindt discloses such a feature, and the teachings of DeWindt would not have suggested modification of the Mamo dilator.

Claim 38 also contains additional elements not addressed by the Office Action, which are not taught or suggested by either Mamo or DeWindt. For example, Mamo and DeWindt fail to disclose or suggest a dilator for widening a path for a stimulation lead to travel through an epidural region proximate a spine of a patient. In contrast, Mamo discloses a dilator for implantation of a sacral stimulation lead through a foramen of the sacrum in a patient.[7]

For at least these reasons, the Office Action has failed to provide a prima facie case of obviousness for claim 38 as required to support a rejection under 35 U.S.C. §103(a). Applicant respectfully requests withdrawal of the rejection of claim 38 and dependent claims 39-45.

Independent Claim 46

As discussed with respect to independent claim 1, the applied references fail to disclose or suggest an elongated dilator, wherein at least a portion of the conical distal tip has a substantially oblong cross-section. Specifically, neither Mamo nor DeWindt discloses such a

[6] Mamo et al., abstract.

feature, and the teachings of DeWindt would not have suggested modification of the Mamo dilator.

Claim 46 also contains additional elements not addressed by the Office Action, which are not taught or suggested by either Mamo or DeWindt. For example, Mamo and DeWindt fail to disclose or suggest a kit including a stimulation lead, wherein a distal end of the stimulation lead has a substantially oblong cross-section and includes at least one electrode. In contrast, Mamo discloses a stimulation lead having a generally round cross-section.[8]

For at least these reasons, the Office Action has failed to provide a prima facie case of obviousness for claim 46 as required to support a rejection under 35 U.S.C. §103(a). Applicant respectfully requests withdrawal of the rejection of claim 46 and dependent claims 47-50.

Dependent Claims 2-15, 17-37, 39-45 and 47 -50

Dependent claims 2-15, 17-37, 39-45 and 47 -50 are patentable over the applied references for at least the reasons discussed above with respect to independent claims 1, 16, 38 and 46, from which they depend. With respect to claim 23, Otten fails to overcome the deficiencies of Mamo in view of DeWindt as discussed with respect to independent claim 16. Furthermore, the dependent claims recite numerous elements not addressed by the Examiner and not found in the prior art.

For example, as recited by claim 20, the applied references fail to disclose or suggest attaching a syringe to the needle, prior to inserting the guidewire into the needle, and attempting to inject fluid into the epidural region via the syringe and the needle to evaluate a position of the needle.

In light of the clear differences between the independent claims and cited references, Applicant reserves further comment with respect to the dependent claims.

For at least these reasons, the Office Action has failed to establish a prima facie case for non-patentability of Applicant's claims 1-50 under 35 U.S.C. §103(a). Withdrawal of this rejection is requested.

---

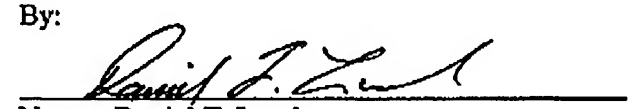
[7] Mamo et al., abstract.
[8] *See*, e.g., Mamo et al., FIGS. 5i-5k.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Applicant does not acquiesce in any of the Examiner's current rejections or characterizations of the prior art, and reserves the right to further address such rejections and/or characterizations.

Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: JUNE 23, 2006

By: 

SHUMAKER & SIEFFERT, P.A.
8425 Seasons Parkway, Suite 105
St. Paul, Minnesota 55125
Telephone: 651.735.1100
Facsimile: 651.735.1102

Name: Daniel T. Lund
Reg. No.: 58,614